

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bruce E. Reidenberg et al.

Application No.: 10/736,043

Confirmation No.: 4015

Filed: December 15, 2003

Art Unit: 3762

For: TRANSDERMAL BUPREORPHINE
DOSAGE REGIMEN FOR ANALGESIA

Examiner: S. E. Kennedy

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
(Check one of the boxes A-D)

- A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
 - (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

- (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. Patent(s) and/or U.S. Patent Application Publication(s) on PTO/SB08 is/are not being submitted.
- B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

3. Cite No(s). _____ is not in the English language. In accordance with 1.98(c), Applicant states:
- An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application , or English-language abstract (or claim) is enclosed.
- The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- A concise explanation of document(s) _____ can be found on the attached sheet.

- 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- 5. Other information being provided for the examiner's consideration follows:

An International Search Report, mailed December 7, 2006, which issued during the prosecution of International Application No. PCT/US03/39792 which corresponds to the present application.

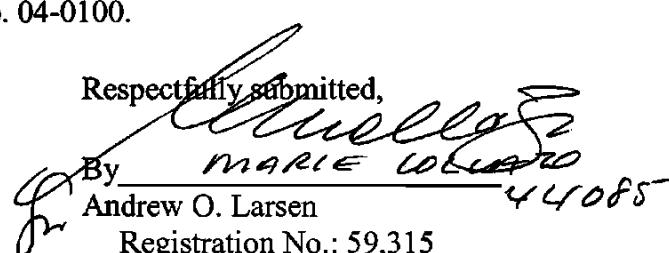
6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated:

Respectfully submitted,

By 
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|------------------------------|---|----|---|--------------------------|------------------------|
| Substitute for form 1449/PTO | | | | Complete if Known | |
| | | | | Application Number | 10/736,043-Conf. #4015 |
| | | | | Filing Date | December 15, 2003 |
| | | | | First Named Inventor | Bruce E. Reidenberg |
| | | | | Art Unit | 3762 |
| | | | | Examiner Name | S. E. Kennedy |
| Sheet | 1 | of | 1 | Attorney Docket Number | 02755/100J533-US1 |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------------|-----------------------|--|------------------|---|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | MM-DD-YYYY | | |
| AA* | US-20010002259-A1 | | 05-31-2001 | Reder et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|------------------|---|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | MM-DD-YYYY | | |
| BA | WO-2003/079945 | | | | |
| BB | WO-2004/103317 | | | | |
| BC | WO-2005/011579 | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|-----------------------|---|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | CA | REIDENBERG et al., "Physiologic Effects of Buprenorphine Transdermal System (BTDS) Dose Escalation in the Young, Healthy Elderly and elderly Hypertensive Subjects," BIOSIS, 7 March 2001; XP002389136; Meeting Abstract | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|